

Remarks

Claims 14-18 and 20-23 are pending and stand rejected. By the foregoing Amendment, claims 14, 18 and 23 are amended and claim 22 is canceled. Entry of the Amendment, and favorable consideration thereof, is earnestly requested.

The Examiner has rejected claims 14-18 and 20-23 under 35 U.S.C. §103 as unpatentable over WO 98/23229 5,899,938 to Sklar et al. in view of U.S. Patent No. 5,693,418 to Luscombe et.al. Specifically, the Examiner cites Sklar for disclosing a ligament shim comprising a body (48) having a first and second ends being substantially planar, the first and second ends having a length and a central width, the length being longer than the central width, at least a first surface and a second surface extending from the first end to the second end and substantially parallel to the axis, at least first surface being arc shaped, and two outwardly rounded surfaces extending from the first end to the second end (Figures 8 & 9). See Office Action p. 2. The Examiner *confirms* that Sklar does NOT disclose a shim hole. *Id.* The Examiner cites Luscombe for teaching a shim comprising a hole 5 extending from the first surface to second surface, the body being devoid of further opening. Applicant respectfully disagrees that these references render the present claims obvious, for the following reasons.

Generally, Sklar does not disclose the Applicant's claim element of shim hole, and there is no teaching or suggestion therein to incorporate a shim hole or other opening (such as the suture opening of Luscombe) to secure the shim in position, as Sklar already achieves this by use of a locking member or screw plug to squeeze and push the ligament against the wall of the opening, as described in more detail below.

Sklar generally discloses placement of one or more graft ligaments 28 are placed within an opening 24 formed in a bone. See Sklar p.p. 8-9, Figs. 1&2. In the embodiment

shown in Fig. 1 and 2, three graft ligaments 28 are contained within a rigid sleeve 22 with protrusions or spikes 42, 44. *See id.* A rigid locking member 32, which is a pivotally movable rocker arm 34, is inserted into the space between the graft ligaments 28 and the inner wall of the opening 24. When turning the locking means 32 (as can be seen in Fig. 2), the sleeve 22 containing the graft ligaments is squeezed against the inner wall of the opening 24 and thereby locked. In the embodiment shown in Fig. 3 of Sklar, the locking member is a conical expansion plug 46 which is inserted into the space, and similarly, the graft ligaments are somewhat deformed and squeezed or pushed against the inner wall of the opening 24. *See id.* at p. 9. Sklar teaches a sleeve and plugs or pegs 46, preferably threaded such that as the plug is screwed into place, the plug engages the sleeve in a wedge-like manner to force the sleeve against the interior wall of the opening. *See id.* In another embodiment, Sklar discloses screwing the plug 46 such that the ligament is forced against the wall of the opening. *See id.*

In the embodiments shown in Fig. 4 and 5 of Sklar, the locking member 34 is contained within a sleeve 22 and the two ligaments 28 are disposed between the sleeve 22 and the remaining space in the opening 24. *See Sklar* at p. 10. When turning the locking means as shown in Fig. 5, the same principle is performed, i.e. the graft ligaments 28 are squeezed or pushed against the wall.

As repeatedly shown in the various embodiments of Sklar, the basic principle of locking the graft ligaments is to insert a rigid locking member in the space between the graft ligaments 28 and the inner wall of the opening 24 formed in the bone. Movement of the rigid locking member squeezes or pushes the graft ligaments against the inner side of the wall of the opening in the bone. The shape of the graft ligaments adapts to the shape of the rigid locking member. *See*, for example, when passing from Fig. 1 to Fig. 2 or from Fig. 4 to Fig. 5 of Sklar.

In Fig. 7, the graft ligament engagement means comprises plate means 48 which is

movable transversely within the bone opening. See Sklar at p.11 (bottom) – p. 12. Fig. 7 shows a single plate having, on a first surface, one or more concavities for nesting one or more graft ligaments respectively. See Sklar at p. 12. The locking means are manipulated to bear against plate to move it into engagement with graft ligaments and secure them against the sidewall. As shown in Fig 8, Sklar discloses screwing the plug 46 threaded partly into the bone and engaging plate such that the ligament is compacted against the wall of the opening. (See p.12-13.)

Hence, Sklar teaches squeezing or pushing ligaments into the wall of an opening in a bone, by use of a rigid locking member, forcing them to adapt to the shape of the locking member, as detailed above. Sklar teaches use of concavities to nest ligaments only within one surface of plate, and only in combination with use of the aforementioned locking means on the other side of the plate.

In contrast, the present claims require the shim is maintained in place with respect to the graft ligament(s) by using a suture passing through a shim hole. See Application, e.g. at pp. 6-8, Fig. 13. All of the pending claims require a shim hole extending from the first surface to the second surface which allows suspension of the shim by a suture passing through the shim hole with respect to surrounding bone. *Id.* This novel feature allows the shim of the present invention to better accommodate one or more ligaments or ligament strands while still allowing suspension of the shim with respect to the surrounding hole via a shim hole. Support for this is found in specification at page 6, lines 18-20 to page 7, line 4; page 7 lines 17-22; and page 8, lines 4-13. Sklar does not disclose this feature, and there is no teaching or suggestion therein to incorporate an opening (such as the suture opening of Luscombe) to serve as a shim hole for Sklar, as Sklar requires no further aid in securing the shim in position as it already utilizes a locking member or screw plug to squeeze and push the ligament against the wall of the opening. As the ligament in Sklar is already jammed against the wall, incorporating a feature of a shim hole to aid in securing the shim (via suture) is useless and

unnecessary, and there would be not motivation for one of skill in the art to modify Sklar in this respect. Moreover, even if a shim hole was incorporated into Sklar, one would not arrive at the present invention in which the shim hole acts to allow suspension of the shim with respect to the surrounding bone, as is required by all claims. See claims 14 and 18 as amended herein. A shim hole in Sklar would be useless and nonfunctioning as the shim is already pushed up against the graft ligament(s) against the wall of the opening in the bone, and therefore the shim hole could not be used to suspend the shim by a suture passing there-through.

The other reference cited by the Examiner, Luscombe, generally relates to a suture anchor device for anchoring suture material to bone, including a suture opening to receive a suture for attachment through the device to the bone. See Luscombe col. 2, lines 25-30. Luscombe's disclosure fails to remedy these aforementioned defects in Sklar, and further there is no motivation to incorporate its teachings into Sklar, including its teaching of a suture opening into Sklar where it would serve as a shim hole. Specifically, Luscombe teaches edges which are designed to fit into adjacent bone structure, specifically sharp edges. See Figs. 3 & 6, Figs. 9 and 10 (#4), and Fig. 23 (#105). Thus, there would be no motivation to combine into the shim of Sklar, elements from Luscombe which is directed to a structure unsuitable for use as a shim in as much as the sharp edge would likely cut through a shimmed ligament. Accordingly, one of ordinary skill in the art would not be motivated to combine the teachings of Luscombe, non-operative as a shim, into the device of Sklar. Accordingly, claims 18-21 and 23-24 are not obvious.

Further, Applicant's independent claim 14, and its dependent claims 15-17 and 20-21, require the element that at least the first surface is arc-shaped overall. While Sklar discloses concavities to nest ligaments (Fig. 7), they are concavities within the otherwise flat surface of the plate. Thus, Sklar does not disclose an arc-shaped surface required by these claims. With respect to claim 18 and its dependent claim 23, it is

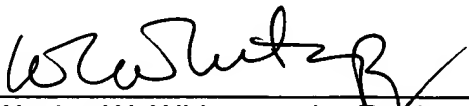
required that the first surface and the second surface are both arc-shaped and are opposed surfaces extending inwardly toward each other adapted to receive one or more ligaments on opposing sides of the body. While Sklar discloses one or more concavities in one surface, it does not disclose opposed inwardly arcing surfaces each for receiving graft ligaments. Moreover, as Sklar requires that the surface opposite to the graft ligament receive the locking member or screw plug. (See Fig. 8), it in fact teaches away from both surfaces capable of receiving ligaments.

Conclusion

It is respectfully submitted that claims 14-18, 20-21, and 23, all claims remaining in the application, are in order for allowance, and early notice to that effect is respectfully requested.

Respectfully submitted,

April 25, 2006



Wesley W. Whitmyer, Jr., Registration No. 33,558
Helen M. Limoncelli, Registration No. 51,950
Attorneys for Applicant
ST.ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, CT 06905-5619
203 324-6155